510(k) SUMMARY

JUN - 5 2006

General Information

Submitted by:	Televere Systems 16275 South Monterey Road, Suite K Morgan Hill, CA 95037 Phone: 408.778.1700 Fax: 408.778.1733
Contact Person:	Mr. Randell Quaal 16275 South Monterey Road, Suite K Morgan Hill, CA 95037 Phone: 408.778.1700 Fax: 408.778.1733 Email: rquaal@tigerview.com
Date Prepared:	April 14, 2006

Device Name

Trade Name:	TigerView Professional
Common Name:	Picture archiving and communications system
Classification Name:	System, Image Processing, Radiological, 21 CFR 892.2050

Predicate Device

Manufacturer	Product Name	510(k) No.
EagleSoft, A Patterson Co.	EagleSoft ChairSide Software Application	K982422
Tau Corp.	TigerScan/TigerView	K955237

Device Description

TigerView Professional is an image management system that allows the physician to acquire, display, edit (e.g., resize, adjust contrast, crop, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. TigerView Professional runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a Network Adaptor, USB port, PCI slot, parallel port, memory card, S-video port on a video capture card, or SCSI card.

Intended Use

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Technological Comparison

TigerView Professional, TigerScan/TigerView, and EagleSoft ChairSide are each software applications that have similar indications for use and overall function and perform in a similar manner with respect to image processing systems (i.e. PACS).

Testing

TigerView Professional has been demonstrated to perform as intended.

Conclusions

TigerView Professional is substantially equivalent to legally marketed Image Processing Systems (i.e. PACS).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 5 2006

Televere Systems
% Ms. Melissa Mahall
Director, Regulatory Affairs
Bio-Reg Associates, Inc.
6304 Belmont Circle, Bldg 2
MOUNT AIRY MD 21771

Re: K061035
Trade/Device Name: TigerView Professional
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 14, 2006
Received: April 14, 2006

Dear Ms. Mahall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K061035

Device Name: TigerView Professional

Sponsor Name: Televere Systems

Indications for Use:

TigerView Professional is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). In addition, TigerView Professional enables the storage of clinical notes, audio recordings, and clinical exam data.

It is intended to acquire, display, edit (e.g., resize, adjust contrast, crop, annotate, etc.), review, store, print, and distribute images using standard PC hardware.

Prescription Use ☒ (21 CFR 801 Subpart D) ~~And~~/Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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